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Shaughnessey Code

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ECOLOGICAL EFFECTS BRANCH REVIEW

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TYPE PRODUCT(S): I, D, H, F, N, R, S Fungicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. S. Lewis (21)

PRODUCT NAME(S) Ronilan WP (vinclozolin)

COMPANY NAME BASF Corporation

SUBMISSION PURPOSE Proposed redistratin of use on grapes

SHAUGHNESSEY CODE	CHEMICAL AND FORMULATION	% A.I.
113201	Vinclozolin (WP)	50%

EEB REVIEW

Chemical: Ronilan (Vinclozolin)

100 Submission Purpose and Labeling Information

100.1 Submission Purpose and Pesticide Use

The registrant, BASF Corporation Chemicals Division Agriculture Chemicals Group has submitted an application for registration of Ronilan WP Fungicide (vinclozolin) on grapes.

100.2 Formulation Information

Active ingredient: Vinclozolin WP

3-(3,5-dichlorophenyl) 5-ethyl-5-methyl-2,4-oxazolidinedione 50%

Inert Ingredients: 50%

100.3 Application Methods,Directions, and Rates

APPLICATION: By ground equipment in 50-200 gallons of dilute spray solution per acre.

DIRECTIONS: May be applied up to four times through the growing season. Applications: first; 5-50% bloom, second; berries at pea-size (prior to bunch closing), third; beginning of fruit softening, fourth; as needed prior to harvest. Ronilan must not be applied within 30 days of harvest.

RATES: Ronilan WP is applied at 1½ - 2 pounds per acre. No more than 8 pounds of Ronilan WP may be applied per acre per season.

100.4 Target Organism

Ronilan fungicide is a protectant material for the control of bunch rot of grapes caused by Botrytis sp..

101 Hazard Assessment

101.1 Discussion

The registrant, BASF Corporation has submitted an application for the registration of Ronilan fungicide on grapes. Approximately 875,000 acres of grapes are planted in the United States.

A rate of 1½ - 2 pounds per acre is recommended. The maximum application rates is 8 pounds (4 lbs/acre a.i.) of Ronilan WP per season. Four applications are allowed per season. Ronilan may not be applied within 30 days of harvest, during rain, by air, or through irrigation equipment.

Under aerobic soil conditions with alkaline (pH 7.4), Vinclozolin is reported to have a half-life of 3-4 days. In slightly acid soil (pH 6.8) the chemical is reported to have a half-life of 3-7 weeks (EFB Submission of the Registration Standard for Strawberries 1980). In anaerobic soil, vinclozolin has a half-life of six months. In sterile soil it is longer. This implies that relatively long half-lives are to be expected.

Studies on field dissipation of vinclozolin after repeated applications in one season show residues would build up in the soil from year to year when used at the higher rates. Furthermore, with the application of soil fertilizer, the acidity of the soil may increase and subsequently extend the soil half-life of the chemical. This could in turn increase the duration of exposure to wildlife using the treated area.

101.2 Likelihood of Adverse Effects on Nontarget Organisms

TERRESTRIAL SPECIES:

Available acute and subacute toxicity data indicate that technical vinclozolin is practically nontoxic to birds. An avian acute oral LD_{50} for bobwhite quail is reported to be > 2,510 mg/kg. Avian Dietary LC_{50} studies are reported to be > 5620 ppm for bobwhite and > 5629 ppm for mallard duck (Fink 1978).

The acute toxicity data on rats suggests that vinclozolin has a low toxicity for mammals. Acute oral LD_{50}s of > 10 g/kg and > 13 g/kg are reported.

Data submitted concerning the toxicity of vinclozolin to honey bees does not satisfy EEB data requirements. However, The data suggests that the chemical is not more than slightly toxic to honey bees.

The primary concern is the adverse effects of this chemical on avian reproduction. Available data indicate that vinclozolin poses a potential chronic hazard to birds. The chemical may effect egg production and egg fertility at dietary concentration of 5 ppm (J. Tice 1982). The Canadian Wildlife Service has found evidence that vinclozolin affects avian testicular development (Memo from R. Balcomb 1984). Officials have recommended, on the basis of available reproduction data, that the chemical not be registered in Canada.

EEB has reviewed a special study protocol submitted by the registrant (BASF Wyandotte Corp.) which investigates the effects of vinclozolin on reproduction in mallard ducks (EEB Memo from L. Turner, October 10, 1986). This study was initially requested by the Canadian Wildlife Service following their review of standard reproduction studies.

After an initial application of vinclozolin at a maximum rate of 1.0 pounds a.i. per acre, estimated residues on avian food items would range from 7 ppm on fruit to 240 ppm on short grass (based on nomograph values of Kenaga). These residue levels are well below acute toxicity values for birds. However, they exceed reproductive effect levels. Furthermore, up to four applications can be made per growing season which will likely increase the residue levels on avian food items.

At least 29 bird species are reported to use grapes. In summer the dense foliage provides good cover and nesting sites for song birds. The bark of grapevines is often used in nest building, (Wildlife Utilization of Cropland, Gusey and Maturgo, 1973). The use period under the proposed registration (first week in May through the end of July) may encompass the breading season for several of these bird species.

The initial exposure level is estimated at 58 pmm (from Kenega values for forage and insects). A half-life of 14 days is estimated from GW data. The length of the simulation, (period of application) could range from nine to eleven weeks depending on weather conditions.

EEB's Fate Simulation Model indicates that after four applications of vinclozolin within 70 days, the average residue level on potential food items would be 59.2 ppm and the maximum residue level would be 105.0 ppm. (See attachment B). These levels far exceed reproductive effect levels for birds.

AQUATIC ORGANISMS:

In 1985 two acute toxicity freshwater fish studies were reviewed but did not fulfill EEB requirements due to insolubility of the test material. The 96-hour LC_{50} value for bluegill sunfish was = 47.3 ppm and the LC_{50} value for rainbow trout was > 18.0 ppm. In 1986 EEB reviewed four additional acute toxicity studies. Two 96-hour rainbow trout studies had LC_{50} values of 2.84 ppm and > 13.6 ppm for measured concentrations. Two bluegill sunfish studies had LC_{50} values of > 3.4 ppm for measured concentrations and > 68.1 ppm for nominal concentrations.

None of these six studies fulfill EEB freshwater fish requirements because of insolubility of the test material, the percent a.i. was not reported, the test temperature was too high, and/or measured test concentrations were not used. Therefore these studies must be repeated.

Two 96-hour freshwater fish acute toxicity studies (one rainbow trout and one bluegill sunfish) are required. if insolubility is a problem, the use of a flow-through test system and/or acceptable solvents in a static test are recommended.

The LC_{50} value for Daphnia magna was determined to be 3.65 mg/l, indicating moderate toxicity. This study fulfills the guideline requirements for aquatic invertebrates.

The estimations of aquatic EEC (see attachment A) provides a value of 6.7 ppb in a pond 6 feet deep with residues being derived from drift and runoff. This value is below levels which would be expected to adversely affect nontarget aquatic organisms for an acute as well as a chronic basis. This conclusion is based on the EEC being less than .01 of the Daphnia LC_{50}. (6.7 ppb < 36.5 ppb).

101.3 Endangered Species Considerations

Approximately 85 percent of the grapes grown in the United States are located in California. A small portion of the acreage is also located New York, Washington, and several other states around the country.

The primary concern with vinclozolin is its potential adverse affects on avian reproduction. EEB's Endangered Species files show 14 federally listed species of birds in California. The time of application (the first week in May through the end of July) may coincide with the breeding periods of many bird species in the state. The American perigrine falcon and the bald eagle could potentially be exposed to the chemical under the proposed registration through ingestion of exposed prey species.

The yellow-shouldered blackbird could be exposed to vinclozolin if used on grapes in Puerto Rico. These birds are reported to nest within feeding range of vineyards (Biological Opinion on the use of Ethroprop on grapes and brussel sprouts USFWS September, 1987). The extent of the potential adverse affects cannot be assessed without additional data.

On the basis of toxicity data and calculated EECs, risk to federally listed non-avian species is not expected.

101.4 Adequacy of the data

The existing data are not adequate to assess the potential negative effects to nontarget organisms.

In order to assess the hazard of vinclozolin to avian species and aquatic organisms, EEB requires the following data: Two freshwater fish 96-hour acute toxicity studies, an avian reproduction study as discussed above, and pending the results, a monitoring study of residues on avian food items may also be required.

103 Conclusions

Negative effects of vinclozolin on egg production, egg fertility and on male testicular development were reported at exposure levels below the levels that could potentially be found on avian food items after one application. Residue levels after repeated applications are expected to be higher.

Multiple applications of Vinclozolin under a relatively short period of time poses a potential chronic hazard to avian species using treated areas. The chemical's extended half-life, potential for residue build up in soil and on food items, and relatively large area of application increases the risk to birds.

EEB has reviewed the proposed registration for the use of Ronilan WP (vinclozolin) on grapes. EEB is unable to complete the risk assessment for this use because pertinent avian reproductive data, avian food item residue data and fish acute toxicity data are lacking. In order to assess the risks associated with this use EEB requires the following data:

1) Two 96-hour freshwater fish acute toxicity studies (one rainbow trout and one bluegill sunfish).

2) An avian reproduction study as discussed above.

3) Pending the results of the avian reproduction study, a residue monitoring study of avian food items may also be required.

Reviewed by

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Date: 10/30/89

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Attachment A

EEC CALCULATION SHEET

I. For un-incorporated ground application

A. Runoff

1 lb(s) x 0.01 (1% runoff) x 10 (A) (from 10 A. drainage basin) = 0.1 lb(s) (tot.runoff)

EEC of 1 lb a.i. direct application to 1 A. pond 6-foot deep = 61 ppb

Therefore, EEC = 61 ppb x 0.1 (lb) = 6.1 ppb

II. For incorporated ground application

A. Runoff

___ lb(s) ÷ _____ (cm) (depth of incorporation) x 0.0_ (_% runoff) x 10 (A) (10 A d.basin) = _____ lb(s) (tot.runoff)

Therefore, EEC = 61 ppb x _____ (lbs) = _____ ppb

III. For aerial application (or mist blower)

A. Runoff

1 lb(s) x 0.6 (appl. efficiency) x 0.01 (1% runoff) x 10 (A) (10 A. d.basin) = 0.06 lb(s) (tot.runoff)

B. Drift

1 lb(s) x 0.05 (5 % drift) = 0.05 lb(s) (tot. drift)

Tot. loading = 0.06 lb(s) (tot. runoff) + 0.05 lb(s) (tot. drift) = 0.11 lb(s)

Therefore, EEC = 61 ppb x 0.11 (lbs) = 6.71 ppb

Attachment B

A PROGRAM FOR PESTICIDE FATE SIMULATION

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name	Ronilan
Initial concentration (ppm)	58
Half-life	14
A number of application	4
Application interval	15
Length of simulation (day)	70

DAY	RESIDUE (PPM)
0	58
1	55.19832
2	52.53198
3	49.99443
4	47.57946
5	45.28113
6	43.09384
7	41.01219
8	39.03111
9	37.14572
10	35.3514
11	33.64375
12	32.0186
13	30.47194
14	29
15	85.59916
16	81.46431
17	77.52918
18	73.78415
19	70.22002
20	66.82805
21	63.59993
22	60.52774
23	57.60397
24	54.82141
25	52.17327
26	49.65305
27	47.25457
28	44.97194
29	42.79958
30	98.73216
31	93.96292
32	89.42404
33	85.10443
34	80.99348
35	77.0811
36	73.35771
37	69.81417
38	66.44182
39	63.23235
40	60.17792
41	57.27104
42	54.50457
43	51.87173
44	49.36608
45	104.9815
46	99.91035
47	95.08418
48	90.49115
49	86.11999
50	81.95998
51	78.00091
52	74.2331
53	70.64729
54	67.23468
55	63.98691
56	60.89604
57	57.95447
58	55.15498
59	52.49073
60	49.95517
61	47.5421
62	45.24558
63	43.06
64	40.97999
65	39.00046
66	37.11655
67	35.32364
68	33.61734
69	31.99346
70	30.44801
Maximum residue	104.9815
Average residue	59.19646